

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

To:

see form PCT/ISA/220

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43bis.1)**

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/EP2004/010538

International filing date (day/month/year)
20.09.2004

Priority date (day/month/year)
30.09.2003

International Patent Classification (IPC) or both national classification and IPC
A61F2/34

Applicant
TECHNISCHE UNIVERSITÄT MÜNCHEN

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



European Patent Office
D-80298 Munich
Tel. +49 89 2399 - 0 Tx: 523656 epmu d
Fax: +49 89 2399 - 4465

Authorized Officer

Josten, S

Telephone No. +49 89 2399-2338



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WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITYInternational application No.
PCT/EP2004/010538

10/574183

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material:

- ☐ a sequence listing
- ☐ table(s) related to the sequence listing

b. format of material:

- ☐ in written format
- ☐ in computer readable form

c. time of filing/furnishing:

- ☐ contained in the international application as filed.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/EP2004/010538

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 2, 3

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the whole application or for said claims Nos. 2, 3

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐ has not been furnished

☐ does not comply with the standard

the computer readable form

☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/EP2004/010538

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has:
- ☐ paid additional fees.
 - ☐ paid additional fees under protest.
 - ☒ not paid additional fees.
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is
- ☒ complied with
 - ☐ not complied with for the following reasons:
4. Consequently, this report has been established in respect of the following parts of the international application:
- ☐ all parts.
 - ☒ the parts relating to claims Nos. 1, 4-15
-

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, Inventive step or Industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	4,7,8,10,14
	No: Claims	1,5,6,9,11,12,13,15
Inventive step (IS)	Yes: Claims	
	No: Claims	1, 4-15
Industrial applicability (IA)	Yes: Claims	1, 4-15
	No: Claims	

2. Citations and explanations

see separate sheet

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Re Item IV.

1. The present application comprises the following three inventions:

- a) the acetabular liner according to independent claim 1, followed by dependent claims 4 to 12 and 15, and the method of manufacturing an implant according to independent claim 13, followed by dependent claim 14,
- b) the acetabular liner according to independent claim 2, followed by dependent claims 4 to 12 and 15, and the method of manufacturing an implant according to independent claim 13, followed by dependent claim 14, and
- c) the acetabular liner according to independent claim 3, followed by dependent claims 4 to 12 and 15, and the method of manufacturing an implant according to independent claim 13, followed by dependent claim 14.

The above-mentioned three inventions of the present application are not so linked that they form a single general inventive concept. The single general inventive concept linking several inventions according to different independent claims can be defined by the common features of these claims. In the present case, the features in common between independent claims 1, 2 and 3 are the following:

An acetabular liner for receiving a femoral head fixed on a stem component comprising:
an outer surface;
an inner surface being concave and forming a cavity adapted to receive the femoral head; and
a rim surface located circumferentially along the top edge of the liner and joining upper edges of the inner and outer surfaces, the rim surface having at least one elevated portion and at least one non-elevated portion.

These features, however, are not novel since they are known from each of the documents cited in the Search Report.

As to D1 (=US-B-6290727); see Figures 1 to 4; see the elevated portion at both sides of the apex 18; see the non-elevated portion 52.

As to D2 (=US-A-2003/0050703; see Figure 2; see the elevated portions between the

two cut aways 36; see the non-elevated portions 36.

As to D3 (=US-A-4950299); see Figure 2; see the elevated portions at reference numeral 28; see the non-elevated portions at reference numerals 24.

As to D4 (=FR-A-2749162); see Figure 4; see the elevated portion 202; see the non-elevated portion formed by the rest of the rim surface.

Consequently, there is no single general inventive concept linking present independent claims 1, 2 and 3 and the application, therefore, does not meet the requirements of Article 13.1 PCT.

Re Item V.

2. The following documents have been cited in the Search Report:

D1: US-B1-6 290 727 (KELLER ARNOLD ET AL) 18 September 2001 (2001-09-18)

D2: US 2003/050703 A1 (BURROUGHS BRIAN R ET AL) 13 March 2003 (2003-03-13)

D3: US-A-4 950 299 (NOILES DOUGLAS G) 21 August 1990 (1990-08-21)

D4: FR-A-2 749 162 (FAUVY ALAIN) 5 December 1997 (1997-12-05)

3. An acetabular liner according to the features of claim 1 is known from each of the documents cited in the Search Report.

D1 discloses a concave portion of the transitional area at least at one side of the lowest part of the cut-off edge 2 in Figure 2.

D2 discloses two concave portions in Figure 2.

D3 discloses four concave portions at both sides of the two lowest parts of the rim in Figure 2.

D4 discloses a concave portion of the transitional area in Figure 4 (compare Figure 4 of the present application with Figure 4 of **D4**).

Thus, claim 1 does not meet the requirements of Article 32(2) PCT.

4. The features of claims 5, 6, 11, 12, 13 and 15 are known from **D2** and the features of claim 9 are known from **D4**. Thus, claims 5, 6, 9, 11, 12, 13, and 15 do not meet the requirements of Article 33(2) PCT.
5. The features of claim 14 cannot be seen as involving an inventive step since the use of milling cutters is customary with the manufacturing of implants and comes within the scope of the customary practice followed by persons skilled in the art. Claim 14, therefore, does not meet the requirements of Article 33(3) PCT.
6. Claims 7 and 8 each attempt to define a feature (i.e. the bevelled surface) by a result to be achieved (claim 7: such that a femoral neck first contacts an inner edge of the bevelled surface and then contacts the entire bevelled surface; claim 8: so formed that a snap fit between the femoral head and the liner is provided over the entire circumference of the cavity of the liner). Thus, Claims 7 and 8 are drafted in functional terms, i.e. they indicate the result to be obtained without defining the means necessary for achieving the desired result. Such a formulation is not allowable since the man skilled in the art would have to employ an inventive step in order to find a solution to the problem posed. The claims should rather specify the technical features of the bevelled surface which are essential for leading to the result. Thus, claims 7 and 8 do not meet the requirements of Article 6 PCT..

Claims 10 and 11 are not clear (Article 6 PCT), since these claims do not only define an acetabular liner per se but its relationship to the neck of a stem component which is not part of the claimed acetabular liner. For reasons of clarity, claims 10 and 11 should be made dependent upon claim 15 which relates to a combination of a liner, a cup and a femoral component.

As far as the dependent claims 4, 7, 8 and 10 can be understood, these claims do not appear to involve an inventive step thus not meeting the requirements of Article 33(3) PCT.